Applicants' Remarks

The examiner's response includes five sections: (1) Claim rejections in view of the previous amendments; (2) Claim rejections to correct dependency of Claims; (3) Rejections under 35 U.S.C. § 102 in view of King; and (4) Claim rejections in view of 35 U.S.C. § 103 base on possible differences in ownership or inventorship; and (5) Claim rejections under 35 U.S.C. § 103 in view of King. Applicants respond below to each of these sections.

(1) Response to Previous Amendment

Previously amended claim 36 was suggested to be amended to something similar to "An implantable system comprising: a genetic material or protein; and an implantable delivery means for delivering . . ."

Applicants have amended claim 36 to conform to the suggested language by the Examiner. As such the Applicants request the present rejection be removed.

(2) Claim Objections (Dependency)

Claims 39 and 43 were objected to because they are now dependent on cancelled claims. Appropriate correction was required.

Applicants have amended Claims 39 and 43 to be dependent on Claims 36, and 41, respectively. In view of the amendments submitted to correct the dependencies of these Claims, Applicants respectively request the present rejection removed.

(3) Claim Rejections - 35 USC § 102 (In View of King)

Claims **36-38 and 40-45** were rejected under 35 U.S.C §102(b) as being clearly anticipated by King et al. (U.S. Patent 5,103,821, hereinafter "King).

King was cited against claims 36-38 for disclosing implanted functioning S-A nodal cells into the heart with a catheter ("Abstract" and col. 9, line 61-col 10, line 8). The Examiner takes the view that because King discloses implanting entire cells that these cells are functioning nodal cells that necessarily comprise functioning ion channels to support an action potential. The Examiner cites Dokos as evidence that nodal cells necessarily contain functioning nodal cells, and further, because these are living, functional cells, the ion channels are formed of ion channel proteins, coded by RNA, which is coded by DNA. In regard to claim 40, a bolus of cells is delivered the Examiner cites col 9, line 61. In regard to Claims 41-43, the Examiner concludes that since entire cells are delivered, and the claimed components are necessary features of functioning S-A node cells, and that therefore King includes the claimed features. And, in regards to Claims 44 and 45, the Examiner concludes that the implanted cells generate a depolarization wave, thus improve the ability to sense said (depolarization wave) cardiac signal (col. 9, line 62).

As previously indicated by the Examiner, King was cited for disclosing implanting entire cells. King does not teach or suggest that one can use purified and isolated genetic material to accomplish this result. In order to clearly distinguish between the Examiner construction of King that because cells are transplanted, genetic material and ion channel proteins are transplanted, Applicants have amended Claim 36 to indicate "isolated and purified" genetic material are implanted. As previously stated, King does not teach or suggest that one can use isolated and purified genetic material. (Please note genetic material now includes the enumerated list).

In view of the submitted amendments and arguments, Applicants respectively request the present rejection under 35 U.S.C. §103 over King be removed.

(4) Claim Rejections - 35 USC § 103 (Common Ownership and Inventorship)

The examiner has reminded the Applicant that the application includes all current names as joint inventors and that the Examiner presumes that the subject matter of the various claims was commonly owned and invented at the time of the invention.

Applicants affirm that all claims were commonly owned and commonly invented at the time the invention was made for purposes of 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

(5) Claim Rejections - 35 USC § 103 (In view of King)

Claims 39 and 46 were rejected under 35 U.S.C. §103(a) as obvious over King. King was cited for disclosing the essential features of the claimed invention, including providing a catheter with a helical element (Col. 10, line 4) and an implantable pacing electrode in conjunction with a helical element (Col. 10, line 4), and an implantable pacing electrode in conjunction with cell therapy (col. 12, line 54), but does not expressly disclose a hollow helical element, or that the electrode detects signals resulting from the delivered material. The Examiner indicates that it is well known in the pacing arts to provide hollow helical elements to provide the predictable results of concurrent fixation and injection, and to detect signals resulting from a delivered material, such as a pharmacological agent, to provide the predictable results of back-up pacing in case the delivered material is not entirely effective. Therefore, the Examiner concludes it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify King's invention by providing a hollow helical element to provide the predictable results of concurrent fixation and injection, and to detect signals resulting from a delivered material to provide the predictable results of back-up pacing in case the delivered material is not entirely effective.

Applicants rely in part on the previous arguments over King. King was cited for disclosing implanting entire cells. King does not teach or suggest that one can

use isolated and purified genetic material, protein, or genetically engineered cells to accomplish this result. In order to clearly distinguish between the Examiner construction of King because cells are transplanted genetic material and ion channel proteins are also transplanted. Applicants have amended Claim 36 to indicate "isolated and purified" genetic material is implanted. As previously stated, King does not teach or suggest that one can use isolated and purified genetic material or protein. The Examiner should note that genetic material includes DNA encoding an ion channel protein, RNA encoding an ion channel protein, an ion channel protein, or genetically engineered cells containing said DNA encoding an ion channel protein

Independently, the Examiner is inferring many propositions that have been extrapolated from Applicants disclosure without directly citing any reference for these propositions, e.g., that it would be obvious to modify King's invention by providing a hollow helical element to provide the predictable results of concurrent fixation and injection, and to detect signals resulting from a delivered material to provide the predictable results of back-up pacing in case the delivered material is not entirely effective. If the Examiner is relying on personal knowledge then this should be appropriately indicated on the record or the proper references should be cited.

In view of the submitted amendments and arguments, Applicants respectively request the present rejection under 35 U.S.C. §103 over King be removed.

Summary

In view of the submitted amendment to the specification indicating the prior history of the application overcoming the prior art references and objections, Applicants respectfully request the present claims be allowed to issue.

Respectfully submitted,

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Date

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